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L3: E	ntry 3 of 3		File: US	PT	Aug 22, 2000
		US 6107323 A l composition			
Detailed	l Description	Paragraph Table (xy-1-[[2'-(1H-t	etrazol-5-yl)
ethoxyca (3) lact hydroxyg	arbonyl-3-phe cose 86.4 mg	(4) corn starch 20 ose 4 mg (7) carme	dazole-7-ca g alanyl]-N mg (5) pol	rboxylic acid (-(indan-2-y1) <u>gl</u> yethylene glyco	2) N-[N-[(S)-1- ycine hydrochloride 1 2.6 mg (6)
2- 1 mg carboxyl (indan-2 polyethy	ethoxy-1-[[2 late (2) N-[N 2-yl)glycine vlene glycol	-[(S)-1-ethoxycarb hydrochloride (3)	(1) (.+) 1) biphenyl- conyl-3-phen lactose 86. propyl cell	4-yl]methyl]-1 ylpropyl]- 10 m 4 mg (4) corn s ulose 4 mg (7)	
Detailed	d Description	Paragraph Table (xy-1-[[2'-(2,5-	dihydro-5-oxo-
acid (2) glycine glycol 2	N-[N-[(S)-1 hydrochlorid 2.6 mg (6) hyd	g 3-yl)biphenyl-4- -ethoxycarbonyl-3- e (3) lactose 86.4 droxypropyl cellul .4 mg one <u>tablet</u> 1	yl]methyl]- phenylpropy mg (4) cor ose 4 mg (7	1H-benzimidazol 1]-L- 10 mg ala n starch 20 mg	e-7- carboxylic nyl]-N-(indan-2-yl) (5) polyethylene
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L7: Entry 3 of 5 File: USPT Oct 28, 1997

DOCUMENT-IDENTIFIER: US 5681584 A

TITLE: Controlled release drug delivery device

Detailed Description Text (13):

As used herein, the active agents CGS 23885, 25019C, CGS 26529, Zileuton, ONO-LB 457 are defined as follows: CGS 23885 refers to N-hydroxy-N-((6-phenoxy-2H-1-benzopyran-3-yl)methyl)-urea; CGS 25019C refers to 4-[5-[4-(aminoiminomethyl) phenoxy]pentoxy]-3-methoxy-N,N-bis(1-methylethyl)benzamide (Z)-2-butenedioate; CGS 26529 refers to N-[2-[[2-[[4-(4-fluorophenyl)phenyl]methyl]-1,2,3,4-tetrahydro-1-oxo-6-iso quinolinyl]oxo]ethyl]-N-hydroxyurea; Zileuton refers to 1-(1-benzo[b] thien-2-ylethyl)-1-hydroxyurea; ONO-LB 457 refers to 5-[2-(2-carboxyethyl)-3-{6-(para-methoxyphenyl)-5E-hexenyl}oxyphenoxy] valeric acid.

Detailed Description Text (16):

Additional core excipients may include tabletting lubricants, glidants, wetting agents to aid in dissolution of the components, binders, and suspending/thickening agents. Suitable lubricants include, but are not limited to, calcium stearate, glyceryl behenate, hydrogenated vegetable oils, magnesium stearate, mineral oil, polyethylene glycol, sodium stearyl fumarate, stearic acid, talc, and zinc stearate. Suitable glidants include, but are not limited to, fused or colloidal silicon dioxide, calcium silicate, magnesium silicate, talc, and silica hydrogel. Suitable wetting agents include, but are not limited to, benzalkonium chloride, benzethonium chloride, cetylpyridinium chloride, docusate sodium, lecithin, nonoxynol 9, nonoxynol 10, octoxynol 9, poloxamer, polyoxyl 35 castor oil, polyoxyl 40 hydrogenated castor oil, polyoxyl 50 stearate, polyoxyl 10 oleyl ether, polyoxyl 20 cetostearyl ether, polyoxyl 40 stearate, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80, sodium lauryl surfate, sorbitan esters, polyoxyethylene sorbitan fatty acid esters, and Tyloxapol (4-(1,1,3,3tetramethylbutyl)phenol polymer with formaldehyde and oxirane). Suitable binders include, but are not limited to, acacia, alginic acid, carboxymethylcellulose sodium, dextrin, ethylcellulose, gelatin, glucose, guar gum, hydroxyethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, polyethylene oxide, polymethylmethacylates, polyvinylpyrrolidone, pregelatinized starch, sodium alginate, syrup, and zein. Suitable suspending/thickening agents include acacia, agar, alginic acid, bentonite, carbomer, carboxymethylcellulose calcium, carageenan, carboxymethylcellulose sodium, corn starch, dextrin, gelatin, guar gum, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, kaolin, lecithin, magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, pectin, poloxamer, polyethylene glycol alginate, polyethylene oxide, polyvinyl alcohol, polyvinylpyrrolidone, vinyl acetate, powdered cellulose, pregelatinized starch, propylene glycol alginate, silicon dioxide, sodium alginate, tragacanth, and xanthan gum.

Detailed Description Text (18):

The delay jacket typically comprises a binder, an osmotic agent, and a <u>tablet</u> lubricant. Suitable binders include, but are not limited to, acacia, alginic acid, carboxymethylcellulose sodium, dextrin, ethylcellulose, gelatin, glucose, guar gum, hydroxyethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, polyethylene oxide,

polymethylmethacrylates, polyvinylpyrrolidone, pregelatinized starch, sodium alginate, syrup, and zein. Suitable osmotic agents include, but are not limited to, inorganic salts such as sodium, potassium or magnesium chloride, or sodium or potassium hydrogen or dihydrogen phosphate; salts of organic acids such as sodium alginate, sodium ascorbate, sodium benzoate, sodium citrate, edetate disodium, sodium fumarate, sodium or potassium acetate, or magnesium succinate; organic acids such as alginic acid, ascorbic acid, citric acid, edetic acid, malic acid, or sorbic acid; carbohydrates such as dextrates, sorbitol, xylitol, maltitol, mannitol, arabinose, ribose, xylose, glucose, dextrose, fructose, galactose, mannose, sucrose, maltose, lactose, or raffinose; water-soluble amino acids such as glycine, leucine, alaninc or methionine; or miscellaneous others such as magnesium sulfate, magnesium carbonate, urea, saccharin, sodium saccharin, glycerin, hexylene glycol, polyethylene glycol, or propylene glycol; and mixtures thereof. Suitable tablet lubricants include, but are not limited to, calcium stearate, glyceryl behenate, hydrogenated vegetable oils, magnesium stearate, mineral oil, polyethylene glycol, sodium stearyl fumarate, stearic acid, talc, and zinc stearate.

CLAIMS:

5. The device of claim 1, wherein the active agent is selected from the group consisting of theophylline, IGF-I, PTH (1-34), TGF.sub..alpha., TGF.sub..beta.1, TGF.sub..beta.2, TGF.beta..sub.3, IFN.sub..alpha., hybrid IFN.sub..alpha., IFN.sub..gamma., hirudin, heparin, calcitonin, 5-aminosalicylic acid, N-hydroxy-N-((6-phenoxy-2H-1-benzopyran-3-yl)methyl)-urea, 4-[5-[4-(aminoiminomethyl)phenoxy] pentoxy]-3-methoxy-N,N-bis(1-methylethyl)benzamide (Z)-2-butenedioate, N-[2-[[2-[4-(4-fluorophenyl)phenyl]methyl]-1,2,3,4-tetrahydro-1-oxo-6-iso quinolinyl]oxy] ethyl]-N-hydroxyurea, 1-(1-benzo[b]thien-2-ylethyl)-1-hydroxyurea, 5-[2-(2-carboxyethyl)-3-{6-(para-methoxyphenyl)-5E-hexenyl}oxyphenoxy] valeric acid, beclomethasone dipropionate, betamethasone-17-valerate, prednisolone metasulfobenzoate, tixocortol pivalate, budesonide, fluticasone, and metoprolol, or pharmaceutically acceptable salts thereof.

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L7: Entry 2 of 5 File: USPT Apr 2, 2002

DOCUMENT-IDENTIFIER: US 6365185 B1

** See image for Certificate of Correction **

TITLE: Self-destructing, controlled release peroral drug delivery system

Detailed Description Text (55):

The delay jacket typically comprises a binder, an osmotic agent, and a tablet lubricant. Suitable binders include, but are not limited to, acacia, alginic acid, carboxymethylcellulose sodium, dextrin, ethylcellulose, gelatin, glucose, guar gum, hydroxyethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, polyethylene oxide, polymethyl methacrylates, polyvinylpyrrolidone, pregelatinized starch, sodium alginate, syrup, and zein. Suitable osmotic agents include, but are not limited to, inorganic salts such as sodium, potassium or magnesium chloride, or sodium or potassium hydrogen or dihydrogen phosphate; salts of organic acids such as sodium alginate, sodium ascorbate, sodium benzoate, sodium citrate, edetate disodium, sodium fumarate, sodium or potassium acetate, or magnesium succinate; organic acids such as alginic acid, ascorbic acid, citric acid, edetic acid, malic acid, or sorbic acid; carbohydrates such as dextrates, sorbitol, xylitol, maltitol, mannitol, arabinose, ribose, xylose, glucose, dextrose, fructose, galactose, mannose, sucrose, maltose, lactose, or raffinose; water-soluble amino acids such as glycine, leucine, alaninc or methionine; or miscellaneous others such as magnesium sulfate, magnesium carbonate, urea, saccharin, sodium saccharin, glycerin, hexylene glycol, polyethylene glycol, or propylene glycol; and mixtures thereof. Suitable tablet lubricants include, but are not limited to, calcium stearate, glyceryl behenate, hydrogenated vegetable oils, magnesium stearate, mineral oil, polyethylene glycol, sodium stearyl fumarate, stearic acid, talc, and zinc stearate.

Detailed Description Text (62):

The delay jacket typically comprises a binder, an osmotic agent, and a tablet lubricant. Suitable binders include, but are not limited to, acacia, alginic acid, carboxymethylcellulose sodium, dextrin, ethylcellulose, gelatin, glucose, guar gum, hydroxyethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, polyethylene oxide, polymethylmethacrylates, polyvinylpyrrolidone, pregelatinized starch, sodium alginate, syrup, and zein. Suitable osmotic agents include, but are not limited to, inorganic salts such as sodium, potassium or magnesium chloride, or sodium or potassium hydrogen or dihydrogen phosphate; salts of organic acids such as sodium alginate, sodium ascorbate, sodium benzoate, sodium citrate, edetate disodium, sodium fumarate, sodium or potassium acetate, or magnesium succinate; organic acids such as alginic acid, ascorbic acid, citric acid, edetic acid, malic acid, or sorbic acid; carbohydrates such as dextrates, sorbitol, xylitol, maltitol, mannitol, arabinose, ribose, xylose, glucose, dextrose, fructose, galactose, mannose, sucrose, maltose, lactose, or raffinose; water-soluble amino acids such as glycine, leucine, alaninc or methionine; or miscellaneous others such as magnesium sulfate, magnesium carbonate, urea, saccharin, sodium saccharin, glycerin, hexylene glycol, polyethylene glycol, or propylene glycol; and mixtures thereof. Suitable tablet lubricants include, but are not limited to, calcium stearate, glyceryl behenate, hydrogenated vegetable oils, magnesium stearate, mineral oil, polyethylene glycol, sodium stearyl fumarate, stearic acid, talc, and zinc

stearate.

Detailed Description Text (79):

Additional core excipients may include tabletting lubricants, glidants, wetting agents to aid in dissolution of the components, binders, and suspending/thickening agents. Suitable lubricants include, but are not limited to, calcium stearate, glyceryl behenate, hydrogenated vegetable oils, magnesium stearate, mineral oil, polyethylene glycol, sodium stearyl fumarate, stearic acid, talc, and zinc stearate. Suitable glidants include, but are not limited to, fused or colloidal silicon dioxide, calcium silicate, magnesium silicate, talc, and silica hydrogel. Suitable wetting agents include, but are not limited to, benzalkonium chloride, benzethonium chloride, cetylpyridinium chloride, docusate sodium, lecithin, nonoxynol 9, nonoxynol 10, octoxynol 9, poloxamer, polyoxyl 35 castor oil, polyoxyl 40 hydrogenated castor oil, polyoxyl 50 stearate, polyoxyl 10 oleyl ether, polyoxyl 20 cetostearyl ether, polyoxyl 40 stearate, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80, sodium lauryl surfate, sorbitan esters, polyoxyethylene sorbitan fatty acid esters, and Tyloxapol (4-(1,1,3,3tetramethylbutyl)phenol polymer with formaldehyde and oxirane). Suitable binders include, but are not limited to, acacia, alginic acid, carboxymethylcellulose sodium, dextrin, ethylcellulose, gelatin, glucose, guar gum, hydroxyethyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, polyethylene oxide, polymethylmethacylates, polyvinylpyrrolidone, pregelatinized starch, sodium alginate, syrup, and zein. Suitable suspending/thickening agents include acacia, agar, alginic acid, bentonite, carbomer, carboxymethylcellulose calcium, carageenan, carboxymethylcellulose sodium, corn starch, dextrin, gelatin, guar gum, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, kaolin, lecithin, magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, pectin, poloxamer, polyethylene glycol alginate, polyethylene oxide, polyvinyl alcohol, polyvinylpyrrolidone, vinyl acetate, powdered cellulose, pregelatinized starch, propylene glycol alginate, silicon dioxide, sodium alginate, tragacanth, and xanthan gum.

CLAIMS:

- 19. The tablet of claim 1 wherein the first beneficial agent is selected from the group consisting of theophylline, IGF-1, PTH (1-34), TGF alpha, TGF beta 1, TGF beta 2, TGF beta 3, IFN alpha, hybrid IFN alpha, IFN gamma, hirudin, heparin, calcitonin, 5-aminosalicylic acid, N-hydroxy-N-((6-phenoxy-2H-1-benzopyran-3-yl) methyl)-urea, 4-[5-[4-(aminoiminomethyl)phenoxy]pentoxy]-3-methoxy-N, N-bis(1-methylethyl)benzamide (Z)-2-butenedioate, N-[2-[[2-[[4-(4-fluorophenyl)phenyl]methyl]-1,2,3,4-tetrahydro-1-oxo-6-iso quinolinyl]oxy]ethyl]-N-hydroxyurea, 1-(1-benzo[b]thien-2-ylethyl)-1-hydroxyurea, 5-[2-(2-carboxyethyl)-3-[6-(paramethoxyphenyl)-5E-hexenyl]oxyphenoxy]vale ric acid, beclomethasone dipropionate, betamethasone-17-valerate, prednisolone metasulfobenzoate, tixocortol pivalate, budesonide, fluticasone, metoprolol, a pharmaceutically acceptable salt thereof, and combinations thereof.
- 45. The <u>tablet</u> of claim 40 wherein the water-soluble amino acid is selected from the group consisting of <u>glycine</u>, leucine, alanine, methionine, and combinations thereof.

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